72. (New) The system of claim 60 wherein said laser source operates to deliver energy at a wavelength in a range of about 1.88 micrometers.

REMARKS

The above amendments are submitted in response to the Office Action of April 11, 1996 and in accordance with suggestions made by Examiner Shay during an interview held on February 13, 1996. Reconsideration and allowance are requested. The present invention is directed to laser surgical systems employing a particular class of lasers operating in the mid-infrared region (approximately 2 micrometers). These laser sources are generally known as "rare earth lasers." The present inventor has discovered that such rare earth lasers can be coupled to low hydroxyl ion content silica fibers to deliver radiation to a surgical site.

The invention is based, in part, on the discovery that the wavelengths of infrared radiation emitted by rare earth lasers are particularly suited for surgery because such wavelengths in the range of 1.4 to 2.2 millimeters are strongly absorbed in biological tissue. The invention is also based on the discovery that low hydroxyl ion content silica fibers enable the transmission of such wavelengths to remote surgical sites to facilitate removal or repair of biological tissue. When operates in a pulsed mode the systems of the present invention can deliver sufficient energy to remove tissue and when operated in a low power, continuous wave mode, biological tissue repair can be achieved.

During the interview on February 13, 1997, Applicant's request for the declaration of an interference proceeding and the outstanding Office Action of April 11, 1996 were discussed in detail. At the outset, following a discussion of the Boutacoff, *et al.* patents, it was agreed that applicant would withdraw his request for the declaration of an interference proceeding at this time in order to pursue a different set of claims directed to laser surgical apparatus employing low hydroxyl ion content silica fibers. The withdrawal of the presently pending claims renders moot the grounds for rejection under 35 U.S.C. §112, set forth on page 3 of the Office Action. As requested by Examiner Shay, the new set of claims have been carefully reviewed to avoid indefiniteness and new matter issues. All the claims are believed to be clearly supported by the specification of applicant's original filing.

Essentially, Applicant's principal claim now recites a laser surgical system including a laser energy source operating at a wavelength in the range of about 1.4 - 2.2 micrometers coupled to a low hydroxyl ion content silica fiber.

During the interview (at which the inventor, Dr. Edward L. Sinofsky, was present), the history of this invention was discussed. More specifically, Dr. Sinofsky explained that at the time the invention was made, he was seeking to develop lasers for medical applications and that the existing laser sources were not well suited for this purpose. Although carbon dioxide (CO_2) lasers had been used for surgical purposes, such lasers generated output energy with a wavelength on the order of 10 micrometers. Energy in this wavelength regime was highly absorbed in water and blood. In addition, the available fiber optic systems for delivery of CO_2 laser radiation were unacceptable

(due to toxicity, water solubility and lack of flexibility). Excimer lasers were also known at the time of Dr. Sinofsky's invention, but there were no suitable fiber optic transmission media. Because excimer lasers generate extremely high peak power pulses of radiation, attempts to channel such power into an optical fiber typically resulted in destruction of the fiber itself. Faced with the lack of suitable laser sources, Dr. Sinofsky realized that mid infrared radiation was required and that such radiation would also need to be transmitted through small, flexible, non-toxic glass fibers. Dr. Sinofsky first attempted to utilize a laser source known as a Neodynium: Yttrium-Aluminum-Garnet (Nd:YAG) lasers. This laser was one of a class of new laser materials known as "rare earth lasers." Unfortunately, the Nd:YAG laser produced radiation at a wavelength on the order of 1.06 microns. Although this radiation could be transmitted via an optical fiber, the wavelength penetrated too deeply into biological tissue to permit surgical tissue removal without significant thermal damage to surrounding areas.

After additional experimentation, Dr. Sinofsky concluded that other rare earth lasers operating in the wavelength range of about 1.4 - 2.2 micrometers could achieve biological tissue removal and/or tissue repair without the disadvantages of the shorter wavelength Nd:YAG laser source. In particular, Dr. Sinofsky discovered that the substitution of holmium, erbium or thulium in YAG crystal matrices (or similar crystals) would achieve laser radiation in a desired wavelength range.

To achieve a practical laser surgical system, however, Dr. Sinofsky also had to improve upon the transmission characteristics of silica fibers. At first, the inventor was unable to locate any existing glass fibers that could transmit the required energy levels for

the required distance, which was on the order of ten feet. Following further experimentation and research, Dr. Sinofsky discovered that the attenuation of laser radiation in this wavelength range was greatly affected by the presence of hydroxyl ions in the glass fibers, and, ultimately, discovered that silica fibers with reduced hydroxyl ion contents were capable of delivering the desired energy levels for the required distances to achieve his laser surgical system.

During the February 13, 1997 interview, it was pointed out that none of the prior art references disclosed this invention or even appreciated the problem solved by Dr. Sinofsky. In particular, it was noted that neither of the Boutacoff, *et al.* patents (U.S. Patent No. 5,037,421 or U.S. Patent No. 5,147,354) taught or suggested the use of low *hydroxyl ion content silica fibers*. Moreover, the references cited in the outstanding Office Action against the previously-presented claims did not detract from the patentability of the newly-claimed invention. In particular, it was stressed that the combination of the Malyshev and L'Esperance ('541) references did not teach or suggest the present invention. The L'Esperance '541 reference discloses an eye surgical instrument employing a carbon dioxide laser beam to remove cataracts. It discloses neither the claimed wavelength range nor the use of low hydroxyl ion content optical fibers.

The Malyshev reference describes a method of cutting biological tissues using two lasers with different wavelengths simultaneously. More specifically, Malyshev describes an embodiment in which a carbon dioxide laser (operating at 10 micrometers) is used in conjunction with a Nd:YAG laser (operating at about 1 micrometer). According

to Malyshev, the combined radiation of the two laser sources, when focussed at one point, achieve a synergy that allows cutting of biological tissues.

Although Malyshev attempts to broadly claim two wavelength ranges that achieve this purported synergy (asserting that the wavelength of the first laser may be in the range of 1.5 - 10.6 micrometers and the wavelength of the other laser may be in the range of 0.6 - 1.0 micrometers), there is no suggestion in the Malyshev reference that Rare Earth Lasers in the specific wavelength range of 1.4 - 2.2 are particularly useful for removing or repairing biological tissue and there is certainly no suggestion that radiation of such wavelengths can be effectively transmitted over long distances using low hydroxyl ion content silica fibers.

Thus, for all the reasons above, it is believed that the newly-presented claims are patentably distinct from the prior art references and early reconsideration and passage to allowance are requested.

It is noted that the previous Office Action cited two related patents and a pending related application as being further grounds for rejection of the prior claims under the judicially created doctrine of obviousness-type double patenting. Reconsideration of this position is requested in conjunction with the examination of the newly-presented claims. It is believed that both of the issued patents are specifically drawn to laser systems for removal of atherosclerotic plaque. The present claims are directed to surgical systems for removal or repair of biological tissue, a patentably distinct invention. If the Examiner

believes that a Terminal Disclaimer is still required, a telephonic interview is requested in order to discuss this matter.

Respectfully submitted,

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